COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 11-VIII-2004
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NOT FOR PUBLICATION

COMMISSION DECISION

of 11-VIII-2004

granting marketing authorisation for the medicinal product for human use "Ariclaim - duloxetine hydrochloride" under Council Regulation (EEC) No 2309/93

(Text with EEA relevance)

ONLY THE GERMAN TEXT IS AUTHENTIC

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1], as amended by Commission Regulation (EC) No 649/98[2], and in particular Article 10(2) thereof,

Having regard to the application submitted by Boehringer Ingelheim International GmbH, on 26 June 2003, under Article 4(1) of Regulation (EEC) No 2309/93, concerning the medicinal product,

Having regard to the opinion of the European Agency for the Evaluation of Medicinal Products, formulated by the Committee for Proprietary Medicinal Products on 24 March 2004,

Whereas:

(1) The medicinal product "Ariclaim - duloxetine hydrochloride" complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3] as amended by Directive 2002/98/EC[4] and by Directive 2003/63/EC[5].

(2) It is therefore appropriate to authorise its placing on the market.

(3) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

[1] OJ L 214, 24. 8. 1993, p. 1.
[2] OJ L 88, 24.3.1998, p. 7.
[3] OJ L 311, 28.11.2001, p. 67.
[4] OJ L 33, 8.2.2003, p. 30.
[5] OJ L 159, 27.6.2003, p. 46.

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorization referred to in Article 3 of Regulation (EEC) No 2309/93 is hereby granted in respect of the medicinal product, "Ariclaim - duloxetine hydrochloride" whose characteristics are summarized in Annex I hereto. This medicinal product shall be entered in the Community Register of Medicinal Products under the numbers:

EU/1/04/283/001	20 mg-Hard Gastro-Resistant Capsules-Oral use-Blisters (PVC/PE/PCTFE/ALU)-56 capsules
EU/1/04/283/002	40 mg-Hard Gastro-Resistant Capsules-Oral use-Blisters (PVC/PE/PCTFE/ALU)-28 capsules
EU/1/04/283/003	40 mg-Hard Gastro-Resistant Capsules-Oral use-Blisters (PVC/PE/PCTFE/ALU)-56 capsules
EU/1/04/283/004	40 mg-Hard Gastro-Resistant Capsules-Oral use-Blisters (PVC/PE/PCTFE/ALU)-98 capsules
EU/1/04/283/005	40 mg-Hard Gastro-Resistant Capsules-Oral use-Blisters (PVC/PE/PCTFE/ALU)-140 capsules
EU/1/04/283/006	40 mg-Hard Gastro-Resistant Capsules-Oral use-Blisters (PVC/PE/PCTFE/ALU)-2 x 98 capsules

Article 2

The marketing authorization concerning the medicinal product referred to in Article 1 shall be subject to compliance with all the conditions, particularly those relating to manufacture and importation, control and issue referred to in Annex II.

Article 3

The labelling and package leaflet concerning the medicinal product referred to in Article 1 shall conform to Annex III.

Article 4

The period of validity of the authorization issued shall be five years from the date of notification of this Decision. It shall be renewable under the conditions laid down in Article 13(1) of Regulation (EEC) No 2309/93.

Article 5

This Decision is addressed to Boehringer Ingelheim International GmbH, Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland.

Done at Brussels, 11-VIII-2004

For the Commission
Olli REHN
Member of the Commission